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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,994	11/16/2000	James Keddie	MBI-0022	7536

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EXAMINER	
KRUSE, DAVID H	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/713,994	KEDDIE ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,13,14,25,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,13,14,25,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/26/2002, pg1*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed on 7 November 2005.

2. The new Title and Abstract are acceptable to the Examiner and the objections are withdrawn.

3. The objection to claim 14 is withdrawn in view of Applicant's amendment.

4. The rejections under 35 USC § 112, second paragraph are withdrawn in view of Applicant's amendments.

5. The provisional rejection for Double Patenting is now moot, Applicant has cancelled claim 8.

6. The rejection under 35 USC § 120(e) as anticipated by Thomashow *et al* is withdrawn in view of Applicant's amendments to the claims and Applicant's arguments (see page 8 of the Remarks).

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

8. Claims 1, 2 and 13 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 14 July 2005. Applicant's

arguments filed 7 November 2005 have been fully considered but they are not persuasive.

The instant claims are rejected for comprising New Matter. The limitation "wherein the stringent conditions comprise two wash steps for 45 to 60 minutes and wash conditions of 2x SSC, 1% SDS at 65°C" at claims 1 and 13 is not supported by the written description in the specification. Applicant states that support can be found on page 12, line 8 and page 33, line 8 of the specification (page 5 of the Remarks). This is not found to be persuasive because at page 12, line 8, Applicant only lists ranges of conditions as exemplary, and the conditions described on page 33 of the specification do not correspond to that in the claims. See *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481 (CA FC 2000). The specification does not guide one of ordinary skill in the art to these specific stringency conditions for isolating a polynucleotide, but only describes them in part in different sections of the specification.

Applicant argues that with the presently claimed hybridization conditions, one of skill in the art would recognize that the claimed conditions are similar to or more stringent than the conditions identified as stringent in Example 9, 6x SSC at 65°C, of the Written Description Guidelines. Applicant argues that as indicated by the Board of Patent Appeals and Interferences (for example in Appeal No. 2004-2201, Application No. 09/788,476), "[a] person of skill in the art would not expect substantial variation among species encompassed within the scope of the claim because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs, thus, a representative number of species is disclose, since highly stringent hybridization

conditions in combination with the coding function of DNA and the level of skill in the art are adequate to determine that applicant was in possession of the claimed invention. Applicant argues that the presently amended claims adequately describe the genus of transgenic plants (and method of making such plants) that comprise sequences that hybridize to nucleic acid sequences encoding SEQ ID NO: 110. See page 6 of the Remarks.

The specifics of Applicants arguments as directed to Appeal No. 2004-2201, identified by Applicant, will not be addressed because the Board of Patent Appeals and Interferences indicated that this decision was not written for publication and is not binding precedent of the Board. Applicant is reminded that each application is examined upon it's own merits. As directed to Example 9 of the Written Description Guidelines, Applicant's specification at page 33, 1st paragraph, states that conditions of 1x SSC, 1% SDS at 60°C are considered "low stringency hybridization", as the instant claims use 2x SSC, the conditions in the claims would be even lower stringency conditions even with a 5 degree Celsius increase in temperature. In addition, claims 1 and 3 recite that the polynucleotide hybridizes to a polynucleotide that encodes a polypeptide comprising SEQ ID NO: 110. This limitation encompasses a myriad of polynucleotide sequences, not a specific polynucleotide sequence. The instant claims also state that the encoded polypeptide confers greater resistance to a fungal pathogen. The polypeptide of SEQ ID NO: 110 is a plant transcription factor that regulates multiple gene expression. The instant claims do not describe what structural feature of the claimed genus is associated with the claimed function as broadly claimed. The instant

claims encompass functional homologues from any other organism, wherein Applicant does not describe a representative number of species, nor does Applicant describe a structural/functional relationship within the genus. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

9. Claims 1, 2, 13, 14 and 25 remain rejected and claims 28 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 14 July 2005. Applicant's arguments filed 7 November 2005 have been fully considered but they are not persuasive.

Applicant argues that techniques using a known DNA as a probe under stringent conditions were conventional at the time of filing, and identified hybridization conditions in their application that one skilled in the art would recognize as stringent (in fact, more stringent than the "stringent" conditions of 6x SSC at 65°C set forth in the USPTO'S Written Description Guidelines). Applicants argue that they have thus taught a representative number of species of the invention, and it would be a matter of routine for one of average skill to identify and confirm the identity of species of the invention. See page 7, 1st paragraph, of the Remarks. These arguments are not found to be persuasive. The issue of stringency conditions is addressed above. The conditions at claims 1 and 3 would isolate a myriad of polynucleotides encoding unrelated polypeptides, only a small fraction of which could be used to make a transgenic plant having greater resistance to a fungal pathogen than a wild-type plant of the same species. Even if one of skill in the art were to screen isolated polynucleotides for those encoding a transcription factor, the fact that transcription factors regulate a myriad of gene encoded functions would still require undue trial and error experimentation, see Riechmann *et al* 2000 cited on page 14 of the Office action mailed 30 July 2002.

Applicants argue that they have identified that unique identifying feature of the conserved domain of the protein encoded by SEQ ID NO: 15 (SEQ ID N0: 110), amino acid coordinates 18-39, in Figure 1. Applicant argues that conserved domains are well-known in the art as functional and structural features of proteins, for example, the NCBI Conserved Domain Database in its own description notes that conserved domains may be used as predictors of evolutionary relationship and function: "[p]roteins often contain several modules or domains, each with a distinct evolutionary origin and function". Applicants argue that they have also disclosed that the polypeptide encoded by SEQ ID NO: 15 is a Z-LSD-like transcription factor may produce the claimed modified trait since it "could be used to manipulate the defense response in order to generate pathogen-resistant plants". See page 7, 2nd paragraph of the Remarks. Applicant's arguments concerning the "conserved domain" of the protein of SEQ ID NO: 110 is not found to be persuasive because a conserved domain is relative to more than one protein, and in the instant art typically more than just two proteins more often a multitude to proteins with similar functional characteristics. Applicant's identification of a Z-LSD-like transcription factor characteristic does not teach one of skill in the art how to make and use the invention as broadly claimed without undue trial and error experimentation because such transcription factor types regulate many different functions.

Applicants argue that the specification did predict that SEQ ID NO: 15, encoding SEQ ID NO: 110, "could be used to manipulate the defense response in order to generate pathogen-resistant plants" and state that "given the disease and biochemical phenotypes of the knock-out plants, we would recommend overexpressing G896 and

look for the opposite phenotypes in transgenic plants". Applicants state that the declaration of Dr. Reuber, attached, identifies four of eight lines of plants overexpressing G896 that are more tolerant to a fungal pathogen than wild-type control plants, thus confirming these statements by Applicants (page 7, 3rd paragraph of the Remarks). Applicants argue that the data in Dr. Reuber's declaration also address the Examiner's use of the Larkin reference to support the unpredictability of transforming a plant to produce an opposite phenotype, in this particular case, knockout plants that were more susceptible to a fungal pathogen did suggest that an overexpression of SEQ ID NO: 110 would be more resistant to at least one fungal pathogen when the sequence was overexpressed (paragraph spanning pages 7-8 of the Remarks). These arguments are not found to be persuasive. The specification at page 40, lines 32-34, states "For a particular knockout that shows a less beneficial characteristic, it may be more useful to select a plant with an increased expression of the particular transcription factor.". At the first page of Figure 2, for SEQ ID No. 15, a knockout, Applicant teaches an increase in susceptibility to *Fusarium*. The instant specification at pages 38-39 implies to one of skill in the art that other pathogens, specifically *Erisyphe orontii*, *Botrytis cinerea* and *Pseudomonas syringae* pv *maculicola* strain 4326, were also tested on said knockout and that no differences were observed in either susceptibility or resistance compared to the wild-type plant. The Declaration under 37 CFR 1.132 of T. Lynne Reuber (The Reuber Declaration, 2005) has been reviewed and considered by the Examiner. On page 2, item 5, of the Reuber Declaration it states that overexpression of a polynucleotide encoding SEQ ID NO: 110 produced more resistance to *Botrytis cinerea*,

than wild-type control plants, but also states that some lines tested were more susceptible to the fungal pathogen *Fusarium oxysporium* in a similar plant assay. The evidence of the Reuber Declaration is not considered by the Examiner to be sufficient to overcome the instant rejection for the following reasons. First the specification would lead one of skill in the art at the time of the invention to try overexpression the polynucleotide of SEQ ID NO: 15 in a plant to produce a *Fusarium* resistant transgenic plant, not a *Botrytis* resistant transgenic plant. One of skill in the instant art would recognize that the desirability of producing a transgenic plant with *Fusarium* resistance is not coextensive with producing a transgenic plant with *Botrytis* resistance, as the two different fungi have different host ranges and pathogenic effects. See *Brenner, Comr. Pats. v. Manson* 1966, 148 USPQ 689 (US SupCt) at 696 which teaches that a patent is not a hunting license, it is not a reward for the search, but compensation for a successful conclusion. See also *Genentech, Inc. V. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicants argue that they did teach a representative number of species of the invention, did enable one of skill in the art to practice the scope of the presently claimed invention, and did teach that the polypeptide encoded by SEQ ID NO: 115, SEQ ID NO: 110, can confer fungal pathogen resistance in plants (page 8, 2nd paragraph of the Remarks). This argument is not found to be persuasive. It is unclear from the instant specification what species are representative of the genus as asserted by Applicants. It

remains the Examiner's opinion that Applicants failed to enable the claims at the time of the invention contrary to Applicants' assertion as outlined supra.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2 and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cao *et al* (January 1997, Cell, 88:57-63).

Cao *et al* is deemed prior art because the instant claims 1 and 13 are directed to a fungal pathogen resistant transgenic plant comprising a polynucleotide that hybridizes to any polynucleotide that encodes SEQ ID NO: 110 under conditions Applicant admits are low stringency binding conditions and a method of making, as discussed supra.

Cao *et al* disclose a transgenic plant with greater resistance to a fungal pathogen, said transgenic plant comprising a polynucleotide encoding the NPR1 polypeptide at page 61, left column. The polynucleotide disclosed by Cao *et al* would inherently comprises an inducible promoter. Cao *et al* disclose a method of making said transgenic plant by transforming with said polynucleotide and selecting a resistant plant at page 58, right column. Hence, all of the claim limitations have been previously disclosed by Cao *et al.*

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. No claims are allowed.

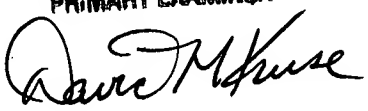
14. Claims 14, 25, 28 and 29 are free of the prior art which neither teaches nor suggests a fungal pathogen resistant plant transformed with a polynucleotide having the sequence of SEQ ID NO: 15 or encoding the polypeptide of SEQ ID NO: 110.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
19 January 2006

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.